

Defendant's Demonstrative Exhibit Regarding The Low Quality and Methodological Unsoundness of Plaintiff's Medical Literature

Exhibit	Study	Plaintiff's Expert's Citation	Methodological Limitation(s) of Study	Selected Study Findings	Miscellaneous
18	Travis J. Miller et al., Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes, 21 JPRAS Open 63 (2019)	Schechter Report at 15 n. 5 (ECF 37-2) Schechter cites Miller et al. for the claim that "100% of transgender women who underwent breast augmentation reported improvement in their gender dysphoria and 'would undergo the operation again.'"	<ul style="list-style-type: none"> • Case study • Retrospective review • Small sample size • Participants lost to follow-up or unable to be contacted • Invariable follow up times • Inadequate monitoring of long-term anatomic and functional consequences • Lack of validated, standardized patient-reported outcome measures • Response bias • Based on single surgeon's experience • Unrelated to genital transition surgery • Focus on surgical outcomes and complications only 	<ul style="list-style-type: none"> • "To date, few surgeons offer dedicated care to transgender patients; hence, a significant portion of the senior author's practice is made up of patients who travel long distance for care. Thus, it is not surprising that several of the patients in this study were lost to follow-up or unable to be contacted...." 73. • "...the PROM inventory was not completed by any of the six patients who experienced a complication. This may lead to some level of response bias in our [] data...." 73. • "[T]his is a single-institution, single-surgeon experience." 72. 	In his deposition, Dr. Schechter disagreed there is a lack of validated, standardized, patient-reported outcome measures for gender affirming surgery because "those measures, probably since this paper was written [2019], either have been or are being developed...." But he could not cite a more recent study in which those measures were discussed. (Schechter Dep. 61:19 – 62:13).

			<ul style="list-style-type: none"> • Not focused on surgery's effect on gender dysphoria • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • "This study is limited by the relatively small sample size and variable follow-up times." 72–73. • "Further studies are needed to determine validated, standardized patient-reported outcome measures for gender-affirming surgery...." 72. 	
19	Alcon, Andre et al., Quantifying the Psychosocial Benefits of Masculinizing Mastectomy in Trans Male Patients with Patient-Reported Outcomes, <i>Plast. Reconstr. Surg.</i> 2021 May 1;147(5):731e-740e (abstract only)	<p>Schechter Report at 15 (ECF 37-2)</p> <p>Schechter writes, "In a prospective study utilizing a validated quality of life assessment tool, Alcon et al. demonstrated significant improvements in quality of life up to 1 year following chest surgery."</p>	<ul style="list-style-type: none"> • Small sample size • Small response rates • Unrelated to genital transition surgery • Unrelated to trans women • Short follow-up time of one-year post-surgery • Relied on self-reporting • Small cohort • Single center focus • Focus on QoL • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • "Although previous studies suggest improved psychosocial outcomes after gender -affirming surgery, there are no transgender-specific instruments available to assess its effects on patient quality of life." • "...the study is limited by a small cohort at a single center..." 	
20	Emily Newfield et al., Female-to-Male Transgender Quality of Life, 15 <i>Quality of Life Research</i> 1447 (2006)	<p>Schechter Report at 16 n. 7 (ECF 37-2)</p> <p>Schechter cites Newfield et al. for the</p>	<ul style="list-style-type: none"> • Retrospective review • Self-selection bias • Internet-based survey 	<ul style="list-style-type: none"> • "We required a unique user name and password to advance beyond the homepage of the website. Although this 	In his deposition, Dr. Schechter agreed that bias would exist due to self-selecting participants "in the extent that these

		<p>claim that: “Those who have received top surgery reported higher QOL (quality of life) scores than those who had not received surgery, statistically significant findings ($p < 0.01$) for the General Health Social Functioning, and all three mental health concepts.”</p>	<ul style="list-style-type: none"> • Lack of diagnostic measurement tools • No measurement of gender dysphoria 	<p>procedure helped prevent duplicate submissions by the same participant, we could not employ more sophisticated computerized systems due to administrative and financial constraints.” 1449.</p> <ul style="list-style-type: none"> • “This survey, as with all research pertaining to the transgender community, is biased by self-selection . . . Clearly, there is a significant opportunity for individuals to falsify their identity in order to participate.” 1454. • “The issues of potential biases are significant and, as such, the results do reported here may not reflect the health and well-being of the entire FTM transgender community, but only the experiences of white, educated, urban FTMs.” 1455. 	<p>are people who have undergone intervention which they found helpful.” (Schechter Dep. 65:3–66:9).</p>
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21	Weigert et al., Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Wellbeing after Breast Augmentation in Male-to-Female Transsexuals, Plastic and Reconstructive Surgery, 132(6)	<p>Schechter Report at 17 n. 8 (ECF 37-2)</p> <p>Schechter cites Weigert et al., stating, “a peer-reviewed study of transgender women found that those who underwent breast reconstruction surgeries experienced statistically significant improvements in their psychosocial well-being.”</p>	<ul style="list-style-type: none"> • Consecutive case series • Small sample size • Participants lost to follow-up or unable to be contacted • Unrelated to genital transition surgery—only reported outcomes of breast augmentation • Not focused on surgery’s effect on gender dysphoria 	<ul style="list-style-type: none"> • “A total of 35 patients were recruited for participation.” 1424. • “All patients completed the BREAST-Q both 3 weeks preoperatively and at a median of 4.0 months . . . following augmentation. Twenty-one patients completed the BREAST-Q again at a median of 20.7 months.” 1425. • “Despite meaningful results on quality of life, this study has some significant limitations. A significant number of questionnaires were missing in the long term (14 of 35 patients). Eight patients were interviewed too early, as less than 6 months had elapsed since the intervention, and six patients were lost to follow-up.” 1428. 	In his deposition, Dr. Schechter stated that is not uncommon to have patients lost to follow-up in this type of study: “survey response rate or being lost to follow-up are situations in which we have to deal with in all areas of medicine and surgery.” (Schechter Dep. at 69:11–70:14.
22	Horbach et al., Outcome of Vaginoplasty in Male-to-Female Transsexuals: A Systematic Review of	<p>Schechter Report at 17–18 n. 9 (ECF 37-2)</p> <p>Schechter states Horbach et al. is “Another peer-</p>	<ul style="list-style-type: none"> • Focus on surgical outcomes and complications • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • In this systematic review of relevant literature: ““Twenty-six studies satisfied the inclusion criteria. The majority of these studies were 	In his deposition, Dr. Schechter stated that the focus of this study was on the operative techniques of GCS, and that “this study is not

	<p>Surgical Techniques, J. Sex Med., 1499–1512 (2015)</p>	<p>reviewed study of transgender women who had vaginoplasty found that study participants’ mean improvement in quality of life after surgery was 7.9 on a scale from one to ten.”</p>		<p>retrospective case series of low to intermediate quality.” 1499.</p> <ul style="list-style-type: none"> • “There is only one study [28] that reports improvement in [quality of life] in patients who underwent penile skin inversion vaginoplasty.” 1506. • “It is impossible to identify the ‘best available’ technique for vaginoplasty in MtF patients due to a lack of high-quality evidence and the heterogeneity of surgical techniques, patient groups, and outcome measures.” 1510. • “There is a need for prospective studies with standardized surgical procedures, larger patient groups, and a longer follow-up period. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and QoL is mandatory for 	<p>speaking or that conclusion is not in reference to the efficacy of gender-affirming surgery.” (Schechter Dep. 74:13–75:4).</p>
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23	Hess et al., Satisfaction with Male-to-Female Gender Reassignment Surgery, Dtsch Arztebl Int, 795–801 (2014)	<p>Schechter Report at 18 n. 10 (ECF 37-2)</p> <p>Schechter cites Hess et al. to state that “Another study of transgender women found that surgical interventions were highly correlated with alleviating gender dysphoria.”</p>	<ul style="list-style-type: none"> • Retrospective, consecutive case study • Participants lost to follow-up or unable to be contacted • Incomplete participant responses • Response bias • No discussion of complications • No preoperative data with which to compare postoperative data • Not focused on surgery’s effect on gender dysphoria • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • “Retrospective study involved consecutive patients who had undergone male-to-female gender reassignment surgery.” 797. • “A total of 119 completed questionnaires were returned This represents a response rate of 46.9%” 797. • “The response rate of less than 50% must be mentioned as a shortcoming of this study.” This may have led to a bias in the results. If all patients who did not take part in the survey were dissatisfied, up to 50.1% and 54.6% would be dissatisfied with aesthetic or functional outcome respectively.” 800. • “It is also possible that the positive results of 	<p>The Center for Medicaid Services’ (CMS) review of GCS-related literature, (Ex. 64), noted the non-response rate of several questions from Hess et al.:</p> <p>Of the participants, 13 (10.9%) reported dissatisfaction with outward appearance and 16 (13.4%) did not respond; three (2.5%) reported dissatisfaction with surgical aesthetics and 25 (21.0%) did not respond; eight (6.7%) reported dissatisfaction with functional outcomes of the surgery and 26 (21.8%) did not respond; 16 (13.4%) reported they could not achieve orgasm and 28 (23.5%) did not respond; four (3.4%) reported feeling completely male/more male than female and 28 (23.5%) did not respond; six (5.0%) reported not</p>

				our survey represent patients' wish for social desirability rather than the real situation. However, this cannot be verified retrospectively." 800.	feeling accepted as a woman, two (1.7%) did not understand the question, and 17 (14.3%) did not respond; and 16 (13.4%) reported that life was harder and 24. 17 (20.2%) did not respond."
24	Hadj-Moussa et al., Feminizing Genital Gender-Confirmation Surgery, Sex Med. Rev., 1–14 (2018)	Schechter Report at 18 n. 11 (ECF 37-2) Schechter cites Hadj-Moussa et al., stating "A recent literature review concluded that in appropriately selected individuals, gender-affirming surgery is effective at improving quality of life, overall happiness, and sexual functioning in transgender women who are diagnosed with gender dysphoria."	<ul style="list-style-type: none"> • Focus on surgical outcomes and complications only • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • "Patients also should be aware that 25% to 80% of patients undergo secondary procedures to optimize voiding or vulvar comesis after vaginoplasty." 8. • "Clinically significant bleeding occurs in 1.7% to 10% of cases." 8. • "Rates of dyspareunia vary widely in the literature, from 0% to 24%." 10. 	
25	Papadopolus et al., Male-to-Female Sex Reassignment Surgery Using the Combined Technique Leads to Increase Quality of Life in a Prospective Study.	Schechter Report at 18 n. 12 (ECF 37-2) Schechter cites Papadous et al. stating: Another recent post-operative and six-	<ul style="list-style-type: none"> • Small sample size • Survey of a single surgeon's patients • Participants lost to follow-up or unable to be contacted • Short follow-up time 	<ul style="list-style-type: none"> • "Between October of 2012 and January of 2014, 49 patients met our inclusion criteria and 47 consented to participate in our study 	

	Plastic and Reconstructive Surgery (2017)	month follow-up survey of transgender female patients found improvements in quality of life in a significant majority of patients.”		<p>before sex reassignment surgery.” 287.</p> <ul style="list-style-type: none">• “The study participants received the first set of questionnaires in person at admission to the hospital, 1 day before their first stage of sex reassignment surgery (time 0). . . . The second set was sent out by mail 6 months after the second stage (time 1) (Fig. 1). This follow-up period ensured enough time had passed for the patients to get accustomed to their final surgical results but also guaranteed high response rates postoperatively. Patients who did not send back the second questionnaire within 4 weeks were encouraged to do so by phone. On average, the questionings were separated by 11.3 ± 3.2 months. In this article, we present the results of the 39 patients who, ultimately, filled out both sets of	
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				questionnaires (return rate, 83 percent).” 287.	
26	Frederick et al., Chest Surgery in Female to Male Transgender Individuals, Ann. Plast. Surg. 2017;78: 249–253	Schechter Report at 18 n. 13 (ECF 37-2) “...one study found that transgender men who received chest reconstruction found that the procedure improved psychosocial well-being and physical well-being among participants.”	<ul style="list-style-type: none"> • Small sample size • No validated method of assessing transgender surgery outcomes • Unrelated to genital transition surgery • Unrelated to trans women 	<ul style="list-style-type: none"> • “There is no validated method of assessing transgender surgery outcomes, because this population presents problems for follow-up. These surgeries are relatively uncommon, the patients often travel long distances for their operation, patients often move and change identity, and transgender patients are particularly concerned with maintaining confidentiality.” 253. • “However, these metrics are not sufficient and do not examine how the patient is integrating into their new life. Transgender and nontransgender cosmetic patients have similar preoperative feelings toward their bodies, similar cosmetic and psychological motivations for surgery, and similar 	Dr. Schechter agrees that the study’s finding of long-term complications in 10.2% of the patients for auxiliary dog ear, and in 13.6% of patients for hypertrophic scar was high compared to his practice. Dep. Shechter at 86:14-25.

				benefits of surgery.” 253.	
27	Agarwal et al., Quality of Life Improvement After Chest Wall Masculinization in Female-to-Male Transgender Patients: A Prospective Study Using the BREAST-Q and Body Uneasiness Test, 71, 651–57 (2018)	Schechter Report at 18–19 n. 14 (ECF 37-2) “Another peer-reviewed study of transgender men who received chest reconstruction found that the procedure improved psychosocial well-being and physical well-being among participants.”	<ul style="list-style-type: none"> • Small sample size • Selection bias • Low response rate • Inadequate follow-up data over extended time • Survey of a single surgeon’s patients • Lack of standardized evaluation metrics • Lack of transgender specific measurement tools • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • “Survey invitations were sent out between one and two weeks preoperatively and again six months postoperatively.” 653. • “Out of 87 eligible patients, a total of 43 completed both the preoperative and postoperative surveys, of which 42 were able to be linked to their chart data through the provided email address, for a response rate of 48%.” 653–54. • “Our study is limited by cohort size, the relative lack of diversity in the respondents (most were White), and the possibility of selection bias in those that were motivated to respond to the surveys. Additionally, the study does not take into account the timing and effect or testosterone therapy, or other 	

				<p>interventions for treating gender dysphoria.” 656.</p> <ul style="list-style-type: none"> • “It is also appreciated that the 6-month follow-up period may not reflect long-term attitudes about the surgery.” 656. 	
28	<p>Olson-Kennedy et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults, JAMA Pediatrics 172(5) (2018)</p>	<p>Schechter Report at 19 n. 15 (ECF 37-2)</p> <p>Schechter cites Olson-Kennedy et al. to point out additional studies that “have reached similar conclusions” supporting GCS.</p>	<ul style="list-style-type: none"> • Small sample size • Focused on transgender youth • Based on 10-minute survey of participants • Cross-sectional study • Unrelated to genital transition surgery • No preoperative data with which to compare postoperative data • No monitoring of long-term anatomic and functional consequences • Lack of validated, standardized patient-reported outcome measures 	<ul style="list-style-type: none"> • “The 10-minute survey collected demographic information, characteristics or surgery, and chest dysphoria.” 6. • “This investigation was limited by the cross-sectional research design; a prospective design collecting data on the same participants before and after surgical intervention would likely yield results more specific to the intervention of chest reconstruction.” at 9. • “An additional limitation of the study was small sample size There could be unknown imbalances between the nonsurgical and postsurgical cohorts that 	

				<p>could have confounded the study findings.” at 9.</p> <ul style="list-style-type: none"> • “Finally, the Chest Dysphoria Scale is not yet validated and may not represent distress or correlate with validated measures of quality of life, depression, anxiety, or functioning.” at 10. 	
34	<p>Buncamper et al., Surgical Outcome after Penile Inversion Vaginoplasty: A Retrospective Study of 475 Transgender Women, Plastic & Reconstructive Surgery (Nov. 2016)</p>	<p>Levine Deposition at 87-91</p> <p>Plaintiff’s counsel confronts Dr. Levine with article he was unfamiliar with to suggest the article was of “moderate” quality.</p>	<ul style="list-style-type: none"> • Retrospective study • Survey of a single institution’s patients • Survey of only one-type of surgical technique • Patients with post-surgery complications may have been lost to follow-up • Does not measure genital dysphoria • Does not measure gender dysphoria 	<ul style="list-style-type: none"> • “A weakness of our study is that patients with complications may have presented at other (international) institutions, which may influence long-term follow-up data.” 1006. • “In our study, comorbid diabetes was associated with a higher risk of local infection after penile-inversion vaginoplasty.” 1006. 	<p>“You need to understand that retrospective studies done by surgeons -- I don't know whether -- you see, I don't know how many people died, how many people suicided. This is talking about the surgical complication rates. It's not talking about anything else. It's not even talking about whether -- about genital dysphonia or gender 22 dysphoria or mental health.” (Levine Dep. at 90:15-22).</p> <p>“The other thing is if the vast majority of articles show inconvincing evidence and if one shows convincing</p>

					evidence, what do we make of that? You see, in science, one study is not enough to prove anything. One study is enough to generate a hypothesis that needs to be tested.” (Levine Dep. at 91:11-16).
88	Van de Grift et al., Surgical Indications and Outcomes of Mastectomy in Transmen: A Prospective Study of Technical and Self-Reported Measures, Plastic and Reconstructive Surgery 140(3) (2017)	<p>Schechter Report at 19 n. 15 (ECF 37-2)</p> <p>Schechter cites Olson-Kennedy et al. to point out additional studies that “have reached similar conclusions” supporting GCS.</p>	<ul style="list-style-type: none"> • Small sample size • Focus on surgical outcomes and complications only • Participants lost to follow-up or unable to be contacted • Lack of validated, standardized patient-reported outcome measures • Unrelated to genital transition surgery • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • “Twenty-six participants (79 percent) returned the survey with self-reported measures.” 419e. • “The present study was limited by the relatively short follow-up period, resulting in uncertain final satisfaction and secondary correction rates. Also, no objective preoperative measures of breast size was used, and no external measure. Such as photography or the surgeon’s evaluation, of the cosmetic outcomes was obtained to relate to the self-reported measures. Lastly, no validated instruments on self-reported outcomes 	

				were available for this population.” 423e.	
87	Smith et al., Sex Reassignment: Outcomes and Predictors of Treatment for Adolescents and Adult Transsexuals, Psychological Medicine, 35(1) 89–99 (2005)	<p>Ettner Report at 10, 12 (ECF 37-1)</p> <p>Ettner cites Smith et al. to support multiple propositions, including that “Decades of careful and methodologically sound scientific research have demonstrated gender affirming surgery is a safe and effective treatment for severe gender dysphoria and, indeed,” “gender-affirming surgery improves virtually every facet of a patient’s life. This includes satisfaction with interpersonal relationships and improved social functioning . . . improvement in self-image and satisfaction with body and physical appearance,” and “surgery improves patients’ abilities to</p>	<ul style="list-style-type: none"> • Old • Participants lost to follow-up or unable to be contacted 	<ul style="list-style-type: none"> • Among survey participants who underwent vaginoplasty, “15 (22.4%) were not completely satisfied, mostly because they considered their vagina not deep or feminine enough. FiveMFs (7.5%) were dissatisfied, because they were unable to achieve sexual arousal or orgasm, or because corrective surgery was needed.” 95. • Among survey participants who underwent breast augmentation, “15 (28.8%) were not completely satisfied, and three felt uneasy about their breasts being too far apart.” 95. 	<p>The Center for Medicaid Services’ (CMS) review of GCS-related literature, (Ex. 64), noted several negative findings in Smith et al.: “Male-to-female patients, however, were more dissatisfied with the appearance of primary sex traits than female-to-male patients. Regarding mastectomy, 27 of 38 (71.1%) female-to-male respondents (not including 11 non-respondents) reported incomplete satisfaction with their mastectomy procedure. For five of these patients, the incomplete satisfaction was because of scarring. Regarding vaginoplasty, 20 of 67 (29.8%) male-to-female respondents (not including 10 non-respondents) reported incomplete satisfaction with their vaginoplasty.” 32.</p>

		initiate and maintain intimate relationships.”			
89	Jarolim et al., Gender Reassignment Surgery in Male-to-Female Transsexualism: A Retrospective 3-Month Follow-up Study with Anatomical Remarks, Journal of Sexual Medicine 6, 1635–44 (2009)	<p>Ettner Report at 10, 12 (ECF 37-1)</p> <p>Ettner cites Jarolim et al. for multiple claims. First, that “Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, gender-affirming surgery improves virtually every facet of a patient’s life. This includes satisfaction with interpersonal relationships and improved social functioning.”</p> <p>And second, that ““Studies have also shown that surgery improves patients’ abilities to initiate and maintain intimate relationships.”</p>	<ul style="list-style-type: none"> • Old • Retrospective review • Short follow-up time (3 months) • Focus on surgical outcomes and complications only • Not focused on surgery’s effect on gender dysphoria • No measurement of gender dysphoria • Inadequate follow-up data over extended time 	<ul style="list-style-type: none"> • “Gender reassignment surgery carries a high risk of micturition problems including urinary stress incontinence and overactive bladder.” 1642. 	
90	Gijs & Brewaeys, Surgical Treatment of gender dysphoria in adults and adolescents:	Ettner Report at 11 (ECF 37-1)	<ul style="list-style-type: none"> • Old • Limited by the overall poor quality 	<ul style="list-style-type: none"> • “Methodologically, however, this conclusion should be carefully qualified. Not one of the 	

	<p>recent developments, effectiveness, and challenges, Annual Review of Sex Research, 18(1) (2007)</p>	<p>Ettner quotes Gijs & Brewaeys findings in support of GCS: “The researchers concluded: ‘Summarizing the results from the 18 outcome studies of the last two decades, the conclusion that gender affirming surgery is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals still stands: Ninety-six percent of the persons who underwent surgery were satisfied and regret was rare.’”</p>	<p>of the literature in this field.</p>	<p>reviewed outcome studies was a controlled one.” 199.</p> <ul style="list-style-type: none"> • “In many studies, sound psychometric instruments were not used. Especially disturbing is that many researchers did not directly measure gender dysphoria as the main outcome variable but instead used derivative measures, for example, satisfaction with surgery, sexual and interpersonal relationships, occupational and global functioning, or quality of life in general.” 199. • “In addition to the design problems of the studies, patient numbers are seriously skewed. A large number of patients who received surgery were lost at follow-up. For the FMs the attrition rate varies between 0% and 81%, with an average of 24%. . . . For the MFs, between 0% and 73% did not participate in the 	
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				<p>follow-up, with an average attrition rate of 39%” 199.</p> <ul style="list-style-type: none"> • “This high dropout rate significantly challenges the external validity or generalizability of our follow-up studies.” 200. 	
91	<p>Ainsworth & Spiegel, Quality of Life of Individuals with and without Facial Feminization Surgery or Gender Reassignment Surgery, Quality of Life Research 19, 1019–24 (2010)</p>	<p>Ettner Report at 12 (ECF 37-1)</p> <p>Ettner cites Ainsworth & Spiegel to support the claim that “Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, gender-affirming surgery improves virtually every facet of a patient’s life. This includes satisfaction with interpersonal relationships and improved social functioning. . . .”</p>	<ul style="list-style-type: none"> • Old • Cross-section study • Internet recruitment • No controls to prevent duplicate responses • Unrelated to genital transition surgery • Lack of validated, standardized patient-reported outcome measures • Response bias 	<ul style="list-style-type: none"> • “Limitations of the overall survey include potential misclassification bias. Participants were asked to complete the survey if they identified themselves as a transgender woman.” 1024. • “We also did not collect data on the medical co-morbidities of our patients. . . . The concern is that those with increasing number of debilitating medical co-morbidities have lower quality of life scores than their counterparts.” 1024. 	<p>The Center for Medicaid Services’ (CMS) review of GCS-related literature, (Ex. 64), noted several problems with this study: “The investigators employed a self-designed Likert-style facial feminization outcomes evaluation questionnaire and a “San Francisco 36” health questionnaire. No citations were provided for the latter. It appears to be the Short-form (SF) 36-version 2. Changes or differences considered to be biologically significant were not pre-specified. Power corrections for multiple comparisons were not provided.” 20.</p> <p>“The investigators reported that there were 247 participants. (The</p>

					<p>numbers of incomplete questionnaires was not reported.) Of the 247 participants, 25 (10.1%) received only primary sex trait reassignment surgery, 28 (11.3%) received facial surgery without primary sex trait reassignment surgery, 47 (19.0%) received both facial and primary sex trait reassignment surgery, and 147 (59.5%) received neither facial nor reassignment surgery.” 20–21.</p>
92	<p>Lawrence, A., Factors Associated with Satisfaction or Regret Following Male-to-Female Sex Reassignment Surgery, Archives of Sexual Behavior, 32(4), 299–315 (2003)</p>	<p>Ettner Report at 12 (ECF 37-1)</p> <p>Ettner cites Lawrence (2003) to support the claim that GCS can lead to “improvement in self-image and satisfaction with body and physical appearance.”</p>	<ul style="list-style-type: none"> • Old • Cross-sectional • Based on single surgeon’s experience • Participants lost to follow-up or unable to be contacted • Response bias • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • “The survey was publicized in advance through electronic media outlets that MtF transsexuals were known to read, and eligible persons were told they could decline to participate by calling a toll-free telephone number or by contacting [the surgeon’s] office by email or by regular mail.” 303. 	

				<ul style="list-style-type: none">• “Information concerning preoperative factors was collected 1-7 years postoperatively, which might have resulted in inaccuracies because of forgetting, or because of coloring of preoperative recollections based on postoperative experiences.” 312.• “Because only 32% of eligible persons returned questionnaires, it is possible that the study participants may not have constituted a representative sample of all those who underwent SRS with [a particular surgeon] during the study period.” 312.• “Persons who experienced especially favorable results might have been more likely to reply because of their feelings of gratitude, and some individuals who experienced regret or unsatisfactory outcomes might have committed suicide, become	
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				institutionalized, or become reclusive; these factors could have biased the results toward more positive outcomes.” 312.	
93	Lawrence et al., Measurement of Sexual Arousal in Postoperative Male-to-Female Transsexuals Using Vaginal Photoplethysmography, Archives of Sexual Behavior 34(2), 135–45 (2005)	Ettner Report at 12 (ECF 37-1) Ettner cites Lawrence et al. (2005) to support the claim that “Studies have also shown that surgery improves patients’ abilities to initiate and maintain intimate relationships.”	<ul style="list-style-type: none"> • Old • Small sample size • Focus on surgical outcome in one area, sexual function • Not focused on surgery’s effect on gender dysphoria • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • “Consequently, the walls of the neovagina in transsexuals are likely to be less highly vascularized than the walls of the vagina in natal women. They are also likely to be less capable of developing vasocongestion than the walls of natal vaginas, because they do not contain cavernous erectile tissue, and because they make only limited contact with residual erectile tissue, and only near the vaginal introitus.” 141. 	
94	Lawrence, A., Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery, Archives of Sexual Behavior 35, 717–727 (2006)	Ettner Report at 12 (ECF 37-1) Ettner cites Lawrence (2006) to support the claim that “Studies have also shown that surgery improves patients’ abilities to	<ul style="list-style-type: none"> • Old • Participants lost to follow-up or unable to be contacted • Selection bias • Focus on surgical outcomes and complications only 	<ul style="list-style-type: none"> • “This study examined preoperative preparations, complications, and physical and functional outcomes of male-to-female sex reassignment surgery (SRS), based on 	The Center for Medicaid Services’ (CMS) review of GCS-related literature summarized some of the results of this study: “Happiness with sexual function and the reassignment surgery was reported to be lower

		<p>initiate and maintain intimate relationships.”</p> <p>Lawrence (2006) used the same data set as Lawrence (2003).</p>	<ul style="list-style-type: none"> • Based on single surgeon’s experience • Response bias • Not focused on surgery’s effect on gender dysphoria • No measurement of gender dysphoria 	<p>reports by 232 patients.” 717.</p> <ul style="list-style-type: none"> • “Of the 727 eligible patients, 310 (43%) could not be contacted.” 719. • “Only 32% of eligible persons returned valid questionnaires, raising the possibility that these participants may not have constituted a representative sample of [the surgeon’s] MtF SRS patients during the 6-year study period.” 725. • “Although the survey questionnaire described the complications of SRS in both lay and professional terms, complications reported by patients may not correspond exactly to what surgically trained persons would regard as complications. Consequently, comparison of the prevalence of self-reported complications in this study with the prevalence of complications in studies 	<p>when permanent vaginal stenosis, clitoral necrosis, pain in the vagina or genitals, or other complications such as infection, bleeding, poor healing, other tissue loss, other tissue necrosis, urinary incontinence, and genital numbness were present. Quality of life was impaired when pain in the vagina or genitals was present.” 17.</p> <p>“Satisfaction with sexual function, gender reassignment surgery, and overall QOL was lower when genital sensation was impaired and when vaginal architecture and lubrication were perceived to be unsatisfactory. Intermittent regret regarding reassignment surgery was associated with vaginal hair and clitoral pain. Vaginal stenosis was associated with surgeries performed in the more distant past;</p>
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				in which assessments were conducted by surgically trained personnel (e.g., those in Table 1) should be undertaken cautiously, if at all.” 726.	whereas, more satisfaction with vaginal depth and width was present in more recent surgical treatment.”
95	Lobato et al., Follow-Up of Sex Reassignment Surgery in Transsexuals: A Brazilian Cohort, Archives of Sexual Behavior 35, 711–715 (2006)	Ettner Report at 12 (ECF 37-1) Ettner cites Lobato et al. to support the claims that GCS can facilitate “greater acceptance and integration to the family” and improves patients’ abilities to initiate and maintain intimate relationships.”	<ul style="list-style-type: none"> • Old • Retrospective review • Small sample size • Participants lost to follow-up or unable to be contacted • Selection bias • Short follow-up period • Lack of a control group • Invariable follow up times • Inadequate monitoring of long-term anatomic and functional consequences • Not focused on surgery’s effect on gender dysphoria • No measurement of gender dysphoria 	<ul style="list-style-type: none"> • “[F]our patients were not eligible and 26 patients (two from a different state) were contacted over the phone or during office visits to the hospital. Seven were lost to follow-up and 19 agreed to participate in the study.” 712. 	
96	De Cuypere at al., Sexual and Physical Health After Sex	Ettner Report at 12 (ECF 37-1)	<ul style="list-style-type: none"> • Old • Retrospective review 	<ul style="list-style-type: none"> • The first aim of this study was therefore to 	

	Reassignment Surgery, Archives of Sexual Behavior 34, 679–90 (2005)	Ettner cites De Cuypere et al. to support the claim that “Studies have also shown that surgery improves patients’ abilities to initiate and maintain intimate relationships.”	<ul style="list-style-type: none"> • Small sample size • Selection bias • Participants lost to follow-up or unable to be contacted • No measurement of gender dysphoria • Response bias 	<p>evaluate the long-term safety of the Ghent hormonal treatment regimen. Secondly, where most studies on transsexual people focus on long-term psychological, surgical, and physical health (Eldh, Berg, & Gustafsson, 1997; Pfafflin “ & Junge, 1998), a surprisingly small number of studies have focused on the sexual life of postoperative transsexuals, although adequate sexual functioning is universally acknowledged as an important component of mental health. Little attention has been given to this subject and, indeed, the vast majority of follow-up studies investigated the sexual functioning only as part of the psychological or the surgical outcome.</p> <p>680</p>	
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				<ul style="list-style-type: none">• “The response rate remains a difficult problem in this type of follow-up research. The patients are either difficult to trace because of the frequent change of residence, or because of unwillingness to participate in interviews of this kind. This implies that researchers can never obtain the profiles of those who fail to respond. This selection bias cannot be ignored.” 689.• “Other limitations of this research are that data were based on self-reports and thus are subjective. However, the evaluation of SRS can be made mainly on the basis of such subjective data, as SRS is intended to solve a problem that cannot be determined objectively.” 689.	
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